

## REMARKS

Claims 27 and 30 have been amended, and claims 34-58 have been added. Consequently, claims 27-58 are currently pending and under consideration. Claims 27-33 stand preliminarily rejected. In response to the Written Opinion of June 29, 2004, Applicant respectfully requests reconsideration.

### **Rejection Under 35 U.S.C. § 102**

Claims 27-29 and 31-33 stand preliminarily rejected under 35 U.S.C. § 102(b) as being anticipated by Weeks (U.S. Patent No. 1,769,872). Applicant respectfully traverses.

Applicant has amended claim 27 to correct a typographical error and to further define the diagnostic and therapeutic instrument as one that “aids in diagnosis and treatment of fibrotic soft tissue,” which includes the mobilization of soft tissue and the introduction of micro-trauma to maintain the mobility within soft tissue structures, such as ligaments and tendons, and to break down and/or prevent fibrous adhesions, commonly known to as scar tissue, from forming. In contrast, Weeks discloses a “massage implement,” which is not adapted to aid in diagnosing and treating fibrotic tissue. Weeks is a superficial massage aid where the undulated surface (10) is rubbed against the skin and used to enhance blood circulation and the return of fluids to the massaged areas. Additionally, Weeks discloses that the “sharpened end 16 of the device may be moved ... upon the eyelids ..., where it is ordinarily inconvenient to properly massage the same.” (Weeks, Pg. 2, Lines 48-53). A device intended for use “upon the eyelids” is not adapted to diagnose and treat fibrotic tissue as this would injure the eyeball underlying the eyelid. Furthermore, Weeks discloses that, when placed on device A, “the pliable applicator 16<sup>a</sup> conforms somewhat better to the contour of the face and provides better massaging action.”

(Weeks, Pg. 2, Lines 76-79). The disclosed ability to use a pliable applicator that conforms to body contours in order to provide better massaging action further indicates that the Weeks device is not adapted to diagnose and treat fibrotic tissue.

Concerning claim 31, the Weeks reference does not disclose all claimed elements. “To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.” MPEP § 2143.03 (*citing In re Royka*, 490 F.2d 981 (CCPA 1974) (emphasis in original)). As an example, Weeks does not disclose a “lower surface being defined by a gradually concavely curved surface extending at least partially and longitudinally along length of said instrument body between said first and second ends thereof.” In contrast, surface 10 of Weeks is provided “with a series of undulations or ribs and grooves 20 [where the] ribs and grooves are of the so-called wave-like formation.” (Weeks, Pg. 2, Lines 5-8). The ribs and grooves 20 of Weeks are not a *gradually* concavely curved as claimed and are sufficiently abrupt to allow five sequential concave portions along the length of top surface 10.

Applicant respectfully asserts that claim 27, as amended, and claim 31 are not disclosed by Weeks and are allowable under 35 U.S.C. § 102(b). Claims 28, 29, 32 and 33 are dependent upon claims 27 and 31 are allowable for at least this reason.

### **Rejections Under 35 U.S.C. § 103**

Claim 30 stands preliminarily rejected under 35 U.S.C. § 103(a) as being unpatentable over Weeks in view of Hashimoto (U.S. Patent No. 5,307,816). Applicant has amended claim 30 to further define the invention and respectfully traverses.

A proper reference in an obviousness analysis must be either (1) in the field of the Applicant’s endeavor, or (2) reasonably pertinent to the inventor’s particular problem. MPEP §

2141.01(a) (*quoting In re Oetiker*, 977 F.2d 1443, 1446 (Fed. Cir. 1992)). Hashimoto is neither in the field of the Applicant's endeavor nor reasonably pertinent to the problem to be solved. Hashimoto is used for blood vessel treatment utilizing ultrasonic radiation, which is not in the field of the Applicant's endeavor. Furthermore, Hashimoto relates to an invasive procedure whereby a catheter is inserted into a blood vessel, which is not reasonably pertinent to the inventor's particular problem and is unrelated to the present invention.

Additionally, there is no evidence of any motivation to combine the Weeks and Hashimoto references as alleged. "The teaching or suggestion to make the claimed combination ... must [] be found in the prior art, and not based on applicant's disclosure." MPEP § 2142 (*citing In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)). "In order to prevent a hindsight-based obviousness analysis, [the Federal Circuit has] clearly established that the relevant inquiry for determining the scope and content of the prior art is whether there is a reason, suggestion, or motivation in the prior art or elsewhere that would have led one of ordinary skill in the art to combine the references." *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 664 (Fed. Cir. 2000).

The Examiner has cited nothing in the references that indicates a motivation to combine, and has merely stated, "it would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify the Weeks' device ... as suggested by Hashimoto et al., for the purpose of providing a therapeutic instrument having resonant capabilities if desired." (Office Action, Pg. 4). However, "The level of skill in the art cannot be relied upon to provide the suggestion to combine references." MPEP § 2143.01 (*citing Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999)).

In fact, there is no motivation to combine Weeks and Hashimoto. Weeks is related to superficial massage of the external surfaces of the body. This does not suggest a need to provide a therapeutic instrument having resonant capabilities (Office Action, Pg. 4), let alone the use of piezoelectric ceramics and resin on the surface of a catheter that is inserted inside the body and vibrated (Hashimoto, column 10, lines 51-57).

Furthermore, even if combined, the combination of Weeks and Hashimoto does not teach all claimed elements in claim 30, as amended. In particular, neither Weeks nor Hashimoto disclose an instrument that “aids in diagnosis and treatment of fibrotic soft tissue.” Applicant respectfully asserts that claim 30, as amended, is allowable under 35 U.S.C. § 103(a) over the cited references.

Applicant respectfully asserts that all pending claims, as amended, are allowable over the cited references and respectfully requests their approval. The Examiner is invited to contact the undersigned directly if it would be helpful to the advancement to this case.

Respectfully Submitted,



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Daniel J. Lueders, Reg. No. 32,581  
Woodard, Emhardt, Moriarty, McNett & Henry LLP  
Bank One Center Tower  
111 Monument Circle, Suite 3700  
Indianapolis, Indiana 46204-5137  
(317) 634-3456